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10/751,069	01/02/2004	Aleksandar Milosavljevic	GMX 071394-CON	1242

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,069	MILOSAVLJEVIC ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-80* is/are pending in the application.

4a) Of the above claim(s) *71-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5,10-3

DETAILED OFFICE ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 61-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is newly applied and necessitated by amendment.

Claim 61 has been amended to recite the limitation of "storing said plurality of samples in a substantially dry and immobilized state in an archive". Review of the application as filed has failed to reveal direct and specific support for the above limitation and as such the amendment is considered to be NEW MATTER. Claims 62 and 63 are also included under this rejection due to their dependence from claim 61.

Claim 62 has been amended to recite the limitation of "providing a repository of stored biological samples derived from mammalian tissue or blood". It is acknowledged that the instant specification discloses that biological samples may be derived from tissue or blood samples, however review of the application as filed has failed to reveal direct and specific support for the more narrow limitation of samples derived from

mammalian tissue or blood. Therefore the above amendment is considered to be NEW MATTER. Claim 63 is also included under this rejection due to its dependence from claim 62.

Claim 64 has been amended to recite the limitation of "providing a database of distinct samples derived from tissue or blood and stored in a substantially dry format". Review of the application as filed has failed to reveal direct and specific support for the above limitation and as such the amendment is considered to be NEW MATTER. Claims 65-67 are also included under this rejection due to their dependence from claim 64.

Claim 68 has been amended to recite the limitation of "providing a database of information corresponding to distinct biological samples derived from patient tissue or blood and stored in a substantially dry format". Review of the application as filed has failed to reveal direct and specific support for the above limitation and as such the amendment is considered to be NEW MATTER. Claims 69 and 70 are also included under this rejection due to their dependence from claim 68.

Double Patenting

The previous provisional rejection of claims 61-70 under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 4, 26-29, and 31-33 of copending Application No. 10/613,434 is withdrawn in view of amendments made to the claims of the instant application. Applicant is advised that the preliminary amendment filled in the copending Application No. 10/613,434 does not appear to comply with 37 CFR § 1.126.

The preliminary amendment expressly canceled claims 1-15 and added additional claims improperly numbered as claims 1-20, however the status of originally filed claims 16-60 in said copending application was not altered by the preliminary amendment. For the purposes of examination in the instant application, the examiner has considered claims 16-60 of copending Application No. 10/613,434 as originally filed, as well as the newly added claims in the preliminary amendment herein referred to as claims 61-80. Applicant is advised that filing an amendment to Application No. 10/613,434 containing a complete listing of claims compliant with 37 CFR § 1.121 and 1.126 would resolve any potential ambiguities regarding what claims are currently pending in said application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would be obvious over, the reference claims. see, e.g., *In re Berg*, 140 F.3d 1428, 46

USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 64-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-29, and 31-33 of copending Application No. 10/613,434. This rejection newly applied and necessitated by amendment. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of copending Application No. 10/613,434 are generically drawn to methods and system of generically providing a repository of biological samples, providing a data base of information on biological samples, and generically selecting a subset of said samples from a biological repository, whereas instant claims 64- 70 are more narrowly drawn to methods and systems of collecting a plurality of samples of material derived from a plurality of biological samples, providing a database of information corresponding to distinct biological samples derived from patient tissue or blood and stored in a substantially dry format in a biological repository and more narrowly selecting a subset of said samples from said biological repository based upon said information corresponding to said distinct samples. See for example lines 3 and 7 of copending claim 26, lines 3 and 9-11 of copending claim 31, lines 4-6, 13, and 14 of instant claim 34 and lines 4-7, 12, and 13 of instant claim 68.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The previous rejection of claims 61-70 under 35 USC 102(e)(2) over Anderson is withdrawn in view of amendments made to the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64 and 68-70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sham et al. This rejection is newly applied and necessitated by amendments to the instant claims.

The instant claims are drawn to a process for remotely conducting a genomics experiment comprising, under control of a service provider, providing a data base of information corresponding to distinct biological samples derived from patient tissue or blood and stored in a substantially dry format in a repository, providing network connection to said database accessible by a client. Under control of a client, accessing said database over a network, selecting a subset of said samples from said biological repository based upon said information corresponding to said distinct samples, and identifying a set of genomic sequences. Further, under control of said service provider, determining if said genomic sequences are present in said samples and informing said client of the determination result.

[Claims 64 and 68]: Sham et al. sets forth a study to determine the relationship between genotype, exemplified with the presence of the HFE mutations, and phenotype, exemplified in hepatic iron index and mobilization iron, in a cohort of patients with hereditary hemochromatosis diagnosed by liver biopsy and other clinical parameters. See Sham et al., Abstract and page 314, column 1, line 1 through page 315, column 1, line 33. The teachings supported that individuals may have hereditary hemochromatosis and homozygous C282Y despite relatively low body iron stores. See Sam et al. Abstract. A data base of patient biopsy information was employed in the disclosed study pertaining to clinically diagnosed hereditary hemochromatosis wherein HFE genotyping had been established. See Sham et al., Tables 1 and 2 and page 316, column 2, lines 8-15. The quantification of hepatic iron was clearly demonstrated as being derived from a substantially biological sample wherein 90.6 μmol/g dry weight hepatic iron was specified for a specific patient. See Sham et al., Abstract and page 315, column 2, lines 7-25. For a set of 61 distinct patients, blood samples were obtained and sent to the Centers for Disease Control and Prevention for genotyping. The genetic testing was performed and the results then transferred to an inventory database. See Sham et al., page 315, column 2, line 36 through page 316, column 7. The results of said results are presented in Tables 1 and 2 of Sham et al. thus demonstrating the reporting of the results from the Centers for Disease Control and Prevention to the authors. Under a reasonably broad interpretation, the authors of Sham et al. are considered to be a client that access a database of information corresponding to distinct biological samples through a network of research associations, which under a

reasonably broad interpretation are viewed as a service provider. The Centers for Disease Control and Prevention provide for the determination of steps and the results were then provided to the authors of Sham et al.

[Claim 69]: Sham et al. discloses a well characterized TaqMan assay used in the genetic testing of a plurality of patient samples submitted to the Center for Disease Control and Prevention. See Sham et al., page 315, column 2, line 36 through age 316, column 2, line 7. Spellman et al. is provided as a supporting document to establish that the TacMan assay reasonably provides for modifying probes that hybridize to specific sequences for determining the presence of a specific sequence using microarray systems. See Spellman et al., page 3275, column 1, first full paragraph, page 3276, column 1, final bridging paragraph through column 2, first bridging paragraph, and page 3277, column 1, final bridging paragraph through column 2, first bridging paragraph. The TaqMan assays as employed by Sham et al. were performed for each individual patient sample and therefore involved the modification of hybridization probes complementary to a set of genomic sequences submitted to the Center for Disease Control and Prevention and were repeated for each patient sample.

[Claim 70]: The above described identification performed by specific genotyping of mutations in the HFE gene reasonably reads on the claimed limitation of identifying distinct biological samples with unique identifiers.

Claim Rejections - 35 USC § 103

The previous rejection of claims 68 and 70 under 35 USC § 103 over Anderson in view of Arvey et al. is withdrawn in view of amendments made to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sham et al. in view of Balaban et al. in view of Spellman et al. This rejection is newly applied and necessitated by amendment.

[Claims 61-63 and 65-67]: As described above, Sham et al. sets forth the methodology and processes drawn to remotely conducting a genomics experiment involving a study to determine the relationship between genotype and phenotype in a

cohort of patients with hereditary hemochromatosis diagnosed by liver biopsy and other clinical parameters in conjunction with testing services provided by the Centers for Disease Control and Prevention. However, Sham et al. does not fairly teach under control of a service provide providing one or more microarrays comprising probes complementary to at least on genome sequence, receiving data over the internet, providing a catalog corresponding to distinct samples stored in a biological sample repository, or accessing said catalog over an internet connection.

Balaban et al. sets for systems and methods drawn to a database model for organizing information relating to, for example, sample preparation, expression analysis of experimental results, and intermediate and final results of mining expression and concentration results. See Balaban et al., Abstract. A preferred embodiment of the disclosed methodologies and systems is drawn to computer system for mining information in regards to gene expression levels. Microarray systems are fabricated with nucleic acid probes and facilitate fluorescent labeling techniques employed in the disclosed computer-aided techniques for gene expression monitoring. See Balaban et al., column 1, lines 53 through column 2, line19 and column 2, lines 33-49. Again, Spellman et al. is provided as a supporting document to establish that the TacMan assay reasonably provides for modifying probes that hybridize to specific sequences for determining the presence of a specific sequence using microarray systems which is in accordance with the disclosed method of Balaban et al. See Spellman et al., page 3275, column 1, first full paragraph, page 3276, column 1, final bridging paragraph through

column 2, first bridging paragraph, and page 3277, column 1, final bridging paragraph through column 2, first bridging paragraph.

The computer related systems involved in the disclosed methods and systems provide for remote operation of performing a selection of samples to be analyzed, constructing experimental microarray systems for an analysis, as well as reporting on experimental results through a computer network system. See for example, Balaban et al., Figures 1, 2A, 2B, column 4, lines 3-27, and column 6, line 2 through column 7, line 10. Further, an alternative embodiment wherein the computer network system is linked via the internet is specifically provided. See Balaban et al., column 6, lines 45-57. An embodiment of the disclosed system is provided wherein a listing of biological samples provided by a host database and under a reasonably broad interpretation reads on the claimed providing and accessing of a catalog corresponding to distinct samples stored in a biological repository. See Balaban et al., column 5, lines 16-25 and column 8, lines 15-29.

Therefore it would have been obvious to one of skill in the art to employ the computer network related methods and systems, as set forth in Balaban et al., for organizing, informing and providing expression data operations with the teachings of Sham et al., drawn to genomics experiment involving a study to determine the relationship between genotype and phenotype in a cohort of patients, so as to efficiently permit the mining of gene expression data from a large number of samples.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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EDJ EDJ

JSB 15 June 2005
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER